

### **REMARKS**

Claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87 and 91-93 are pending, wherein no claims have been amended, added or cancelled. Reconsideration and allowance for the above-identified application are now respectfully requested in view of the following remarks.

The Office Action rejects claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87 and 91-93 under 35 U.S.C. § 103(a) as being unpatentable over McLaughlin (US 6,108,850) and Shimada et al. (US 5,626,837). As Shimada et al. was only cited as allegedly disclosing antimicrobial agents, pH adjustors, stannous fluoride and humectants, the main issues can be addressed and disposed of by identifying the deficiencies of McLaughlin relative to the main elements recited in the claims. Applicants submit that as one considers the totality of what is taught in McLaughlin, it becomes apparent that McLaughlin does not disclose or suggest the combination of elements recited in the claims, either alone or if combined with Shimada et al.

Claim 41 defines a dental bleaching composition that is substantially free of abrasives for bleaching and desensitizing a person's teeth. The bleaching composition comprises a dental bleaching agent in an amount in a range of 10% to about 30% by weight of the dental bleaching composition so as to have a tooth bleaching effect when contacted with a person's teeth, said dental bleaching agent comprising at least one peroxide. The composition also includes potassium nitrate in a range of about 0.01% to about 2% by weight of the dental bleaching composition so as to result in reduced tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is contacted with a person's teeth for a time sufficient to bleach teeth. Finally, the composition includes "a carrier that is substantially free of abrasives into which said dental bleaching agent and potassium nitrate are dispersed such that the dental bleaching composition contains less than 20% by weight of an abrasive, the carrier comprising a solvent and a tackifying agent". McLaughlin fails to disclose or suggest the combination of elements recited in claim 41, and Shimada et al. fails to cure the deficiencies of McLaughlin.

For example, claim 41 requires the combination of a dental bleaching agent, potassium nitrate, and a carrier comprising a solvent and tackifying agent and that is substantially free of abrasives (*i.e.*, so that the dental bleaching composition contains less than 20% by weight of an abrasive). McLaughlin can, when read in its entirety, only be understood as disclosing either 1) a composition that includes an abrasive in combination with a thickener (*see* col. 3, lines 50-61) or 2) a composition that includes neither an abrasive nor a tackifying agent (*see* col. 7, lines 6-

15). McLaughlin cannot be interpreted as disclosing a tackifying agent in combination with a dental bleaching agent and potassium nitrate but without an abrasive.

First, as pointed out in response to the previous Office Action and confirmed by the present Office Action, the only basis for alleging that claim 41 is obvious over McLaughlin is Example 4. Example 4 discloses a toothpaste composition that includes 10% hydrogen peroxide, 1% potassium nitrate, 83.5% of a “paste carrier” of unspecified constituents, and other sundry components that are not germane to the rejection of claim 41 (*i.e.*, “flavoring agent 1%”, “aloe vera 2%”, “titanium dioxide 1%” and “sodium lauryl sulfate 1.5%”). Example 4 further teaches that “the formulation [of Example 4] comprising the bleaching compound is placed on the toothbrush with a catalyst embedded into one or more of the bristles of the brush, or with a catalytic agent embedded in a fabric bonded to the head of the brush”. Col. 7, lines 22-26.

The fact that the composition of Example 4 includes a “paste carrier” and is applied using a “toothbrush” indicates that it is objectively a “toothpaste”. It is well known to those of ordinary skill in the art that “toothpastes” typically include an abrasive. <http://sci-toys.com/ingredients/toothpaste.html> (11/04/09) (“A modern toothpaste has many things to do. It must have abrasives to scour off bacterial films”); <http://www.healthnews.com/dental-health/toothpaste-there-difference-200.html> (11/04/09) (“Toothpaste abrasives scrub away plaque, help remove food stains from teeth, and polish tooth surfaces”). Indeed, McLaughlin also discloses the use of abrasive materials:

In one embodiment, an abrasive material can be used with the composition of the invention. For example a dicalcium phosphate abrasive may be incorporated into the composition (e.g., see U.S. Pat. No. 5,171,564). Example of dicalcium phosphate abrasives include, but are not limited to dicalcium phosphate dihydrate, anhydrous dicalcium, or calcium pyrophosphate. Other abrasives of use with the subject invention include siliceous materials. Examples of such materials include, but are not limited to, silica abrasives, such as precipitated amorphous hydrated silica, and alumina abrasives, such as alumina trihydrate, aluminum silicate, calcined alumina, and bentonite.

Col. 3, lines 37-49. This is further evidence that one of ordinary skill in the art would understand the toothpaste embodiment of Example 4 to include an abrasive material. Moreover, one of ordinary skill in the art would understand the “paste carrier” of Example 4 to include an abrasive material in sufficient quantity as to impart an abrasive action sufficient to clean teeth during brushing (*i.e.*, more than 20%). In view of the foregoing, Applicants submit that claim 41 is

patentable and unobvious over McLaughlin for this reason alone, as Example 4 of McLaughlin does not objectively disclose or suggest a desensitizing dental bleaching composition that includes a dental bleaching agent, potassium nitrate, and a carrier that includes a solvent and a tackifying agent but which is substantially free of abrasives.

Moreover, conspicuously absent from McLaughlin's Example 4 is any mention of a "solvent" or "tackifying agent". As a result, simply referring to Example 4 is insufficient to establish that claim 41 is *prima facie* obvious. The Examiner had to look elsewhere in the specification of McLaughlin to find the missing components of solvent and tackifying agent. However, when one sees the context in which the "thickening agent" (*i.e.*, the alleged "tackifying agent") and water are disclosed in the other sections of McLaughlin, it becomes readily apparent that a thickening agent and solvent are used in combination with an abrasive material.

**When an abrasive material is included** the vehicle may contain water, humectant, surfactant, and a thickener. Examples of humectants are glycerin, sorbitol, and polyethylene glycol (molecular weight 200-1000). Both mixtures of humectants and single humectants can be employed in the composition of the invention. **Thickeners may be incorporated in the abrasive component** such as natural and synthetic gums such as carrageenan, xanthan gum, sodium carboxymethyl cellulose, starch, polyvinylpyrrolidone, hydroxyethylpropylcellulose, hydroxybutyl methyl cellulose, hydroxypropyl methyl cellulose, and hydroxyethyl cellulose.

Col. 3, lines 50-61 (emphasis added).

In all cases where a thickening agent and solvent are mentioned, they are included together with the "abrasive material" (or "abrasive component"). *Id.* Nowhere does McLaughlin disclose or suggest the use of a thickening agent in the absence of the abrasive material. The same argument applies to water (a solvent), which is only mentioned "[w]hen an abrasive material is included". Col. 3, lines 50-51. Accordingly, there is no teaching, suggestion, motivation or other reason that would have prompted one of ordinary skill in the art to modify McLaughlin in order to obtain a dental bleaching composition that includes a dental bleaching agent, potassium nitrate, a solvent and thickening agent but which is substantially free of abrasives. As Shimada et al. was only cited as allegedly disclosing the use of antimicrobial agents, pH adjusters, actives, and humectants, Shimada et al. fails to cure the deficiencies of McLaughlin. Accordingly, claim 41 is unobvious over the combination of McLaughlin and Shimada et al.

All remaining claims similarly claim a dental bleaching composition, or a method of using a dental bleaching composition, that is substantially free of abrasives. The remaining claims are therefore patentable over the combination of McLaughlin and Shimada et al. for at least those reasons given above relative to claim 41. In addition, claims 46, 65 and 81 claim an amount of potassium nitrate (about 0.5%) that is not taught or suggested by McLaughlin. Moreover, claims 59 and 77 claim a range of potassium nitrate (about 0.05-1%) that is neither taught nor suggested by McLaughlin.

The Office Action rejects claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87 and 91-93 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,306,370 (the “370 patent”). In response, Applicants incorporate by reference arguments made in previous amendments explaining that the claims of the present invention define narrowly tailored concentration ranges of potassium nitrate that are neither taught nor suggested by either the claims or the specification of the ‘370 patent. Moreover, Applicants incorporate by reference and refer to the Declaration of Dan E. Fischer under 37 CFR § 1.132 setting forth and explaining that using relatively low quantities of potassium nitrate (*e.g.*, 0.5%) rather than larger quantities (*e.g.*, 3%) was surprisingly and unexpectedly found to reduce tooth and oral sensitivity caused by the dental bleaching agent more effectively than when a higher quantity of potassium nitrate (*e.g.*, 3%) was used. Because potassium nitrate was known to be a desensitizing agent, it would not be obvious that using less potassium nitrate would be more effective as a desensitizing agent than the accepted practice of using more potassium nitrate (*e.g.*, 3%). Therefore, the claims of the present application claim a specifically defined category of dental bleaching compositions that have unpredictably superior results compared to the full range of dental bleaching compositions within the scope of the claims of the ‘370 patent.

For example, claim 1 of the ‘370 patent claims potassium nitrate in an amount “of at least about 0.1%”. According to the specification of the ‘370 patent, the amount of potassium nitrate can be as high as 50% by weight. Col. 6, lines 53-55 (“the inventive compositions may preferably include potassium nitrate in a wide range from about 0.1% to about 50% by weight of the whitening composition”). Accordingly, when the amount specified in claim 1 of the ‘370 patent is interpreted in light of the specification, it is readily apparent that the claimed range of claim 1 is essentially about 0.1-50%. This range is so broad as to hardly be suggestive of the

narrowly tailored ranges set forth in the claims of the present application (*i.e.*, about 0.01-2%, about 0.05-1%, and about 0.5%).

Moreover, the comparative study clearly showed that using an amount of potassium nitrate (*i.e.*, 0.5%) within the narrowly tailored ranges of the present application was far more effective in reducing sensitivity caused by the dental bleaching agent than using an amount outside the ranges (*i.e.*, 3%). If using 3% potassium nitrate is worse in desensitizing teeth than using 0.5% potassium nitrate (or no potassium nitrate), it follows that using more than 3% would also be worse than using 0.5% potassium nitrate. Accordingly, to the extent that using 3-50% potassium nitrate is actually *worse* in desensitizing teeth than using 0.5% potassium nitrate, it follows that the vast majority of potassium nitrate concentrations within the scope of claim 1 of the '370 patent provide unexpectedly and unpredictably *worse* tooth desensitization compared to using an amount of potassium nitrate (*e.g.*, 0.5%) within the narrowly tailored ranges recited in the claims of the present application. That further supports the conclusion that the narrowly tailored ranges recited in the claims of the present application are unobvious over the extremely broad range recited in claim 1 of the '370 patent.

Dependent claim 2 of the '370 patent claims potassium nitrate in a range of about 1% to about 7%. Again, because using an amount of potassium nitrate over a majority of the claimed range of claim 2 (*i.e.*, 3-7%) is surprisingly and unexpectedly *worse* in desensitizing teeth than using an amount of potassium nitrate (*e.g.*, 0.5%) within the narrowly tailored ranges recited in the claims of the present application, it follows that the claims of the present application are unobvious over claim 2 of the '370 patent.

Finally, dependent claims 14 and 16 of the '370 patent claim potassium nitrate in a range of about 0.1% to about 10%. That means that at least 70% of the potassium nitrate concentrations within the scope of claims 14 and 16 (*i.e.*, 3-10%) are surprisingly and unexpectedly *worse* in desensitizing teeth compared to using an amount of potassium nitrate (*e.g.*, 0.5%) within the narrowly tailored ranges recited in the claims of the present application. From this, it logically follows that the claims of the present application are unobvious over claims 14 and 16 of the '370 patent.

Independent claims 13 and 15 do not specify *any* concentration of potassium nitrate and therefore do not suggest including potassium nitrate within the narrowly tailored ranges recited in the claims of the present application. Moreover, as the specification of the '370 patent suggests that using about 3-10% potassium nitrate is "most preferred" for effecting the

desensitizing effect of potassium nitrate (col. 6, lines 57-59), one of skill in the art would not have understood claims 13 and 15 as somehow suggesting the use of an amount of potassium nitrate within the narrowly tailored ranges recited in the claims of the present application.

In response to the argument in the Office Action that the comparative study failed to test the desensitizing effect of potassium nitrate when used in combination with a broader range of dental bleaching agent concentrations, Applicants note that it is the amount of potassium nitrate that is the result-effective variable which controls the desensitization effect of the potassium nitrate, not the amount of dental bleaching agent. It is clear from the comparative study that changing the amount of dental bleaching agent from 10% to 15% had virtually no effect on relative tooth and oral sensitivities. In contrast, changing the amount of potassium nitrate from the accepted and usual 3% to 0.5% had an overwhelming effect on reducing tooth and oral sensitivities. Because changing the amount of dental bleaching agent was found to have little, if any, effect on relative tooth and oral sensitivities, there was no need or reason to test the effect of using 0.5% potassium nitrate in combination with a wide range of different bleaching agent concentrations. Moreover, because the use of three amounts of potassium nitrate (*i.e.*, 0%, 0.5% and 3%) showed the existence of a clear trend relative to reducing relative tooth and oral sensitivities, there was no need or reason to test the effect of using other amounts of potassium nitrate within the narrowly tailored ranges. According to clearly established case law, the detection of a trend in the data will support claiming a broader range of concentrations than the actual data points tested.

In conclusion, Applicants submit that the claims of the present application are unobvious over the claims of the '370 patent because (1) the potassium nitrate ranges recited in claims 1, 2, 14 and 16 of the '370 patent are so broad as to hardly suggest the narrowly tailored ranges recited in the claims of the present application and (2) the comparative study shows that the use of potassium nitrate in an amount (*i.e.*, 0.5%) within the narrowly tailored ranges surprisingly and unexpectedly provided a far greater reduction in relative tooth and oral sensitivities compared to using an amount of potassium nitrate (*i.e.*, 3%) outside the narrowly tailored ranges.

In the event the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or which may be overcome by Examiner amendment, the Examiner is requested to contact the undersigned attorney.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to **Deposit Account**

**No. 23-3178:** (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefore and charge any additional fees that may be required to **Deposit Account No. 23-3178**.

Dated this 16<sup>th</sup> day of November 2009.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "J.M. Gynn", is written over the printed name.

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